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| APPLICATION NO. FILING DATE | | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------------|--------|-------------|----------------------|-------------------------|------------------|--|
| 09/909,667 07/20/2001 | | 7/20/2001 | Stephen D. Kuslich | S85.2-9892 | 1524 | |
| 490 | 7590 | 09/27/2002 | | | | |
| VIDAS, AR | RETT & | STEINKRAUS, | EXAMINER | | | |
| 6109 BLUE (SUITE 2000 | | | PHILOGENE, PEDRO | | | |
| MINNETONKA, MN 55343-9185 | | | | ART UNIT | PAPER NUMBER | |
| | | | | 3732 | 8 | |
| | | | | DATE MAILED: 09/27/2002 | O | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | pplication No | | Applicant(s) | pplicant(s) | | |
|---|--|--|---|--|----------------------------|--|--|
| | | 09/909,667 | /909,667 KUSLICH ET AL. | | | | |
| Office Action Summary | E | xaminer | | Art Unit | | | |
| | | edro Philogen | | 3732 | | | |
| The MAILING DATE of this commu Period for Reply | nication appear | rs on the cove | r sheet with the c | orrespondence ad | dress | | |
| A SHORTENED STATUTORY PERIOD THE MAILING DATE OF THIS COMMUN - Extensions of time may be available under the provision after SIX (6) MONTHS from the mailing date of this com - If the period for reply specified above is less than thirty - If NO period for reply is specified above, the maximum of the period for reply within the set or extended period for reply - Any reply received by the Office later than three months earned patent term adjustment. See 37 CFR 1.704(b). Status | VICATION. Is of 37 CFR 1.136(a) Imunication. (30) days, a reply with statutory period will a by will, by statute, cau |). In no event, how hin the statutory mi pply and will expire use the application | ever, may a reply be tim nimum of thirty (30) days SIX (6) MONTHS from to become ABANDONFI | ety filed s will be considered timely the mailing date of this co | <i>y.</i> ommunication. | | |
| 1) Responsive to communication(s) t | filed on <u>20 July</u> | <u> 2001</u> . | | | | | |
| 2a) ☐ This action is FINAL . | 2b)⊠ This a | action is non-f | inal. | | | | |
| 3) Since this application is in condition closed in accordance with the practice of Claims | on for allowance ctice under <i>Ex</i> | e except for fo parte Quayle | ormal matters, pr , 1935 C.D. 11, 4 | osecution as to th 53 O.G. 213. | e merits is | | |
| 4) \boxtimes Claim(s) <u>1-24</u> is/are pending in the | | | | | | | |
| 4a) Of the above claim(s) is/s | are withdrawn 1 | from conside | ration. | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1-24</u> is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restri | ction and/or eld | ection require | ment. | | | | |
| 9) The specification is objected to by the | ie Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are | | or b) object | ed to by the Exan | niner. | | | |
| | | | - | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12)☐ The oath or declaration is objected to | o by the Exami | ner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim | n for foreign pri | ority under 35 | 5 U.S.C. § 119(a) | -(d) or (f). | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| 1.☐ Certified copies of the priority | documents ha | ve been rece | ived. | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies application from the Interest See the attached detailed Office action | of the priority on | documents ha | ave been received 17.2(a)). | d in this National S | Stage | | |
| 14) ☐ Acknowledgment is made of a claim t | for domestic pr | iority under 3 | 5 U.S.C. § 119(e) |) (to a provisional | application). | | |
| a) The translation of the foreign land 15) Acknowledgment is made of a claim | nguage provisi | onal applicati | on has been rece | eived. | | | |
| Attachment(s) | F · | , | | , | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (F3) Information Disclosure Statement(s) (PTO-1449) P | | 4) 5) 6) | | (PTO-413) Paper No(s atent Application (PTO | | | |
| S. Patent and Trademark Office TO-326 (Rev. 04-01) | Office Action | Summary | | Part of F | Paper No. 08 | | |

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. (6,248,110) in view of Kuslich (5,549,679).

With respect to claim 21, Reiley et al. disclose a device for compacting cancellous bone comprising an inner layer (266) and an outer layer (270,270a), the outer layer defining a flexible material which at least partially surrounds the inner layer, as best seen in FIG.29A, the inner layer defining an elastomeric body (56,266), the inner layer and the outer layer combination define an expandable body adapted to assume a collapsed geometry for deployment into bone and an expandable geometry for compacting cancellous bone (32,268) to form cavity (84), the inner layer defining a substantially hollow chamber (FIG.29A), the inner layer chamber and outer layer defining at least one opening (FIG.29A), the expandable body constructed and arranged to expand from the collapsed geometry to the expanded geometry when a predetermined amount of fill material is placed within the substantially hollow chamber through the at least one opening, the outer layer constructed and arranged to prevent penetration of the inner layer by the cancellous bone encountered during expansion of the expanded body; as best seen in the figures and as set forth in columns 11,12 lines 1-67.

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It is noted that Reiley et al. did not teach of an outer layer including a plurality of pores, which extend therethrough, as claimed by applicant. However, in a similar art Kuslich evidences the use of an expandable bag having an outer layer including a plurality of pores to allow tissue ingrowth while containing material packed into the bag.

Therefore, given the teaching of Kuslich, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the fabric of Reiley et al with the fabric of Kulisch to provide an outer layer with a plurality of pores that allow tissue ingrowth while containing material packed into the bag.

With respect to claims 22-24, Reiley et al disclose all the limitations, as best seen in the Figures, and as set forth in column 17, lines 25-50, column 10, lines 47-67.

With respect to claims 1-20, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

| 5,571,189 | 11-1996 | Kuslich |
|-----------|---------|---------------|
| 6,235,043 | 5-2001 | Reiley et al. |
| 6,187,043 | 2-2001 | Ledergerber |
| 5,674,295 | 10-1997 | Ray et al. |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703)

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308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene September 23, 2002

PEDRO PHILOGENE PRIMARY EXAMINER